

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No: 10/797,354
Appellants: Stefan Moll et al.
Filed: March 10, 2004
Title: DIALYSIS STATION
T.C./A.U.: 3626
Examiner: Linh Giang Le
Confirmation No.: 4286
Notice of Appeal Filed: February 3, 2009
Docket No.: BBMG-100US

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated August 5, 2008 of claims 1-20.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) are provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is B. Braun Medizintechnologie GmbH by virtue of an assignment recorded on July 2, 2004, at Reel/Frame 015535/0810.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal.

III. STATUS OF CLAIMS

Claims 1-20 are pending and stand finally rejected. Claims 1-20 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

As set forth in pending independent claim 1, the presently claimed invention relates to a dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person. With reference to Fig. 1, the specification (all references to the specification refer to the clean copy of the substitute specification) sets forth beginning at page 7, line 12,

a dialysis station with several patient places 10 is illustrated. Each patient place 10 is provided with a corresponding bed or chair 11 as well as with a dialyzer 12. The dialyzer 12 is a dialysis machine connected with the patient's body via a hose system 13 and including, inter alia, a blood pump 14.

The dialyzer 12 is provided with a video terminal 16 comprising a touch screen forming an input/output device for a (non-illustrated) PC operatively connected with the controlling and measuring system of the dialyzer. The dialyzers 12 and the video terminals 16, respectively, are connected with each other and with a central server 20 via a data bus line 17 in order to form an internal network 21. Further, electronic scales 22 for weighing the patient as well as a video terminal 23 arranged at a central physician place 24 are connected with the network 21. A further video terminal 25 may be arranged at an external physician place 26 connected with the internal network 21 by an external network 27. Thus, there is an additional access to the internal network 21 from a remote location.

The server 20 contains a data base and performs the entire management of all machine and patient data.

The dialyzer 12 has a reading apparatus 18. It is a chip card reader for reading out data from a chip mounted on a chip card. The chip card serves to identify the operating person and the patient. By reading the chip card, the operating person and the patient are distinctly allocated to the respective dialyzer.

It is further explained at page 8, line 21 through page 9, line 3 that "[t]he patient information is put to the disposal of the server 20 and the respective physician place 24,26. Instructions to the operating personnel are sent from the physician place 24,26 to the patient place 10. The respective video terminal draws the attention of the patient or the personnel to the arrival of a respective instruction by an alarm. Following the instruction has to be acknowledged by the personnel."

It is explained in the specification at page 11, 7-11, with reference to Figs. 9 and 10, that "[t]he nurse can input her ID number or a password. This is

acknowledged by the OK key 52. Thereupon, the nurse is identified. Pressing the OK key 52 is the acknowledgment of the execution of the instruction at the place of work. With this variant, the screen mask illustrated in Fig. 10 forms the ID input device 18a for identifying the personnel."

A course of treatment using the dialysis station is explained at page 11, line 13 through page 13, line 9. As explained in section 7 on page 12, "7. The instruction of the physician is obeyed, and the completion is again acknowledged by the nurse by inputting her ID code. The physician directly receives a reply as to the execution. The data are stored and can be processed further (e.g., repeat order of 10 ml of medicine X)."

As set forth in pending independent claim 11, the presently claimed invention relates to a dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person. With reference to Fig. 1, the specification sets forth beginning at page 7, line 12,

a dialysis station with several patient places 10 is illustrated. Each patient place 10 is provided with a corresponding bed or chair 11 as well as with a dialyzer 12. The dialyzer 12 is a dialysis machine connected with the patient's body via a hose system 13 and including, inter alia, a blood pump 14.

The dialyzer 12 is provided with a video terminal 16 comprising a touch screen forming an input/output device for a (non-illustrated) PC operatively connected with the controlling and measuring system of the dialyzer. The dialyzers 12 and the video terminals 16, respectively, are connected with each other and with a central server 20 via a data bus line 17 in order to form an internal network 21. Further, electronic scales 22 for weighing the patient as well as a video terminal 23 arranged at a central physician place 24 are connected with the network 21. A further video terminal 25 may be arranged at an external physician place 26 connected with the internal network 21 by an external network 27. Thus, there is an additional access to the internal network 21 from a remote location.

The server 20 contains a data base and performs the entire management of all machine and patient data.

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It is further explained at page 8, line 21 through page 9, line 3 that "[t]he patient information is put to the disposal of the server 20 and the respective physician place 24,26. Instructions to the operating personnel are sent from the physician place 24,26 to the patient place 10. The respective video terminal draws the attention of the patient or the personnel to the arrival of a respective instruction by an alarm. Following the instruction has to be acknowledged by the personnel."

It is explained in the specification at page 11, 7-11, with reference to Figs. 9 and 10, that "[t]he nurse can input her ID number or a password. This is acknowledged by the OK key 52. Thereupon, the nurse is identified. Pressing the OK key 52 is the acknowledgment of the execution of the instruction at the place of work. With this variant, the screen mask illustrated in Fig. 10 forms the ID input device 18a for identifying the personnel."

A course of treatment using the dialysis station is explained at page 11, line 13 through page 13, line 9. As explained in section 2, on page 11, "2. The patient goes to any patient place 10 at all and identifies himself with his card there again. The apparatus automatically begins to prepare itself. . . ." It is further explained in section 7 on page 12, "7. The instruction of the physician is obeyed, and the completion is again acknowledged by the nurse by inputting her ID code. The physician directly receives a reply as to the execution. The data are stored and can be processed further (e.g., repeat order of 10 ml of medicine X)."

As explained on page 13, beginning on line 10, "only the data for the treatment of the respective patient appear on the video terminal 16 of the patient place 10, that the personnel is able to input the protocol and remarks relating thereto directly at the dialyzer 12, that the attention of the personnel is drawn to instructions of the physician directly at the screen, and that the executions thereof are supervised."

As set forth in pending independent claim 17, the presently claimed invention relates to a dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person. With reference to Fig. 1, the specification sets forth beginning at page 7, line 12,

a dialysis station with several patient places 10 is illustrated. Each patient place 10 is provided with a corresponding bed or chair 11 as well as with a dialyzer 12. The dialyzer 12 is a dialysis machine connected with the patient's body via a hose system 13 and including, inter alia, a blood pump 14.

The dialyzer 12 is provided with a video terminal 16 comprising a touch screen forming an input/output device for a (non-illustrated) PC operatively connected with the controlling and measuring system of the dialyzer. The dialyzers 12 and the video terminals 16, respectively, are connected with each other and with a central server 20 via a data bus line 17 in order to form an internal network 21. Further, electronic scales 22 for weighing the patient as well as a video terminal 23 arranged at a central physician place 24 are connected with the network 21. A further video terminal 25 may be arranged at an external physician place 26 connected with the internal network 21 by an external network 27. Thus, there is an additional access to the internal network 21 from a remote location.

The server 20 contains a data base and performs the entire management of all machine and patient data.

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As explained on page 13, beginning on line 10, “only the data for the treatment of the respective patient appear on the video terminal 16 of the patient place 10, that the personnel is able to input the protocol and remarks relating thereto directly at the dialyzer 12, that the attention of the personnel is drawn to instructions of the physician directly at the screen, and that the executions thereof are supervised.”

It is further explained at page 13, beginning at line 5 that “the personnel is able to input measures performed without job instruction at the video terminal 16, which are also transmitted to the server 20 either with or without identification. Furthermore, it is possible to input occurrences appearing during the treatment, e.g., a drop of blood pressure, which are then transmitted to the central computer.”

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-20 are unpatentable under 35 U.S.C. § 103(a) unpatentable over Hogard in view of Ford further in view of Fujimoto.

VII. ARGUMENT

A. Rejection Under 35 U.S.C. §103(a) Based on U.S. Patent No. 6,284,131 in View of U.S. Patent No. 6,269,340 and Further in View of U.S. Patent No. 5,339,821

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,284,131 (Hogard et al.) in view of U.S. Patent No. 6,239,340 (Ford et al.) and further in view of U.S. Patent No. 5,339,821 (Fujimoto). Appellants respectfully traverse these rejections.

"To establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 1 recites: "A dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person, the dialysis system comprising: at least one patient place having a dialyzer, a video terminal, and an ID input device for inputting an identification; a central server including a data base; and at least one physician place equipped with a video terminal, said video terminals of the at least one patient place and the at least one physician place and the server being interlinked with each other and configured such that information on the course of the treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input; wherein the system is configured such that information on the execution of an instruction can be input at the patient place and the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device."

Similarly, independent claim 11 recites: "A dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person, the dialysis system comprising: at least one

patient place having a dialyzer, a video terminal, and an ID input device for inputting an identification; a central server including a data base; and at least one physician place equipped with a video terminal, the video terminals and the server being interlinked with each other and configured such that information on the course of the treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input, wherein the system is configured such that information on the execution of an instruction can be input at the patient place and the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device, and wherein a patient code can be input which allocates the at least one patient place to a patient, the video terminal of the at least one patient place is configured as a user interface for setting and changing parameters of the dialyzer, and the setting and change are stored along with the identity of the executing person."

Independent claim 17 similarly recites: "A dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person, the dialysis system comprising: at least one patient place having a dialyzer, a video terminal, and an ID input device for acknowledging an identification; a central server having a data base and a patient data file stored in the server, the patient data file including indications on the dialyzer determined for a patient as well as on the settings and operational parameters thereof, and the video terminal of the at least one patient place receives the settings and operational parameters from the server and sets them at the dialyzer; and at least one physician place equipped with a video terminal, wherein the video terminals of the at least one patient place and the physician place are connected in an internal communication network, the internal communication network connected with an external communication network to which a video terminal of an external physician place is connected, the video terminals and the server being interlinked with each other and configured such that information on the course of the treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input, wherein the system is configured such that: information on the execution of an instruction can be input at the patient place and the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device; information on occurrences

may be input at the patient place and such input is effected in that the executing person acknowledges his or her identity in the ID input device; and a patient code can be input which allocates the at least one patient place to a patient, the video terminal of the at least one patient place is configured as a user interface for setting and changing parameters of the dialyzer, and the setting and change are stored along with the identity of the executing person."

The Final Office Action acknowledges that Hogard et al. does not teach video terminals and a server configured such that information on the course of treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input. Fujimoto was cited in the January 11, 2008 Office Action as teaching a home medical system equipped with communication equipment to connect to a medical institution side and that it would have been obvious to add these features to Hogard with a motivation of having a home medical system that can undergo a check or inquiry a medial specialist at a medical institution.

Appellants respectfully submit that Fujimoto does not overcome the shortcomings of Hogard et al. The only transmission of information described in Fujimoto is the transmission of test data to be stored in memory and for the doctor to send, and a patient to reply to, a diagnosis inquiry. In neither case is information on the course of treatment callable at a selected patient place, as recited in claim 1. Fujimoto is only concerned with diagnosis and does not teach or suggest the transmission or availability of a course of treatment.

Ford et al. is cited as teaching a storage medium containing a drug library with each pump being associated with a set of associated drug delivery information. Appellants respectfully submit that Ford et al. does not overcome the shortcomings of Hogard et al. and Fujimoto. Ford et al. explains at column 10, line 63 through column 11, line 60 that the pump 10 is connected to a single personal computer 80 as shown in Figure 5. This single PC 80 provides on its screen a Main Menu through which authorized personnel may enter drug configurations and/or operate the pump. Ford et al. fails to teach video terminals of at least one patient place and at least one physician place and a server being interlinked with each other and configured such that information on the course of the treatment at a selected

patient place is callable and instructions for a selected patient place are adapted to be input. Ford et al. teaches only a single PC 80 to call and input information.

Furthermore, none of the cited references, teach or suggest a system configured wherein the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device. The Final Office Action acknowledges that Hogard et al. does not teach or suggest this feature. While Fujimoto was cited in the January 11, 2008 Office Action, the Final Office Action does not cite to Fujimoto as teaching this feature. As explained in the April 11, 2008 Amendment, incorporated herein by reference, the Fujimoto system only taught a patient log in and there is no way to tell if the patient took any actions simply by their logging in to the system.

Ford et al. is cited as teaching a computer interface program that is only accessible by persons who have been assigned a password. While Ford et al. may teach a security log in feature, Ford et al. fails to teach or suggest a system configured wherein the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device. The current application explains at page 10, line 20 through page 11, line 11 of the clean copy of the substitute specification that:

In Fig. 8, the instruction list (list of treatment instructions) is illustrated which appears after touching the symbol 40 in Fig. 6. This list, e.g., includes the times at which a certain treatment at the patient has to be performed, e.g., "measuring the body temperature." After an instruction of the list has been executed, this is acknowledged by the operating person by pressing an acknowledgment key 50 provided at the apparatus as a hardware key.

Figs. 9 and 10 show the screen surface for the subsequent password entry of the personnel. First, the personnel list with the names of the respective nurses appears. The respective nurse may select and touch her name and acknowledge it by pressing the OK key 50. Thereafter, the alphanumeric keyboard illustrated in Fig. 10 appears. The nurse can input her ID number or a password. This is acknowledged by the OK key 52. Thereupon, the nurse is identified. Pressing the OK key 52 is the acknowledgment of the execution of the instruction at the place

of work. With this variant, the screen mask illustrated in Fig. 10 forms the ID input device 18a for identifying the personnel.

The current application further explains in the example of a treatment course beginning at page 11, line 11, that the nurse enters a personal ID at two distinct times. Paragraph 4a explains that "The nurse in charge also identifies herself at the dialyzer." Paragraph 7 explains that "The instruction of the physician is obeyed, and the completion is again acknowledged by the nurse by inputting her ID code." As recited in the current claims and explained in the specification, the completion of an instruction is acknowledged by a user inputting an ID code.

Ford et al. simply provides a security log in feature as explained at column 18, line 59 through column 20, line 49. The system of Ford et al. checks to confirm that a user is authorized to complete a given task, however, Ford et al. is silent on a user acknowledging in any way that an instruction has been executed, let alone by entering a user ID.

For at least these reasons, it is respectfully submitted that the cited references, alone or in any reasonable combination, fail to teach or suggest each limitation of the claimed invention. It is respectfully submitted that independent claims 1, 11 and 17 are in condition for allowance. Claims 2-10, 12-16 and 18-20 each depend from a respective one of the independent claims and are also allowable for at least the reasons set forth above.

VIII. CONCLUSION

In view of the arguments set forth above, all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Such actions are respectfully requested.

Respectfully Submitted,

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Enclosures: Claims Appendix
Evidence Appendix
Related Proceedings Appendix

Dated: April 3, 2009

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The Director is hereby authorized to charge or credit Deposit Account No. 18-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith.

CLAIMS APPENDIX

1. A dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person, the dialysis system comprising:

at least one patient place having a dialyzer, a video terminal, and an ID input device for inputting an identification;

a central server including a data base; and

at least one physician place equipped with a video terminal,

said video terminals of the at least one patient place and the at least one physician place and the server being interlinked with each other and configured such that information on the course of the treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input;

wherein the system is configured such that information on the execution of an instruction can be input at the patient place and the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device.

2. The dialysis system according to claim 1, wherein information on occurrences can be input at the patient place, and an acknowledgment of the input is effected in that the executing person acknowledges his or her identity in the ID input device.

3. The dialysis system according to claim 1, wherein a patient code can be input which allocates the patient place to a patient.

4. The dialysis system according to claim 1, wherein the video terminal of the patient place is configured as a user interface for setting and changing parameters of the dialyzer, and the setting and change are stored along with the identity of the executing person.

5. The dialysis system according to claim 1, wherein the video terminals of the at least one patient place and the physician place are connected in an internal communication network.

6. The dialysis system according to claim 5, wherein the internal communication network is connected with an external communication network to which a video terminal of an external physician place is connected.
7. The dialysis system according to claim 1, wherein a symbol for calling an instruction input at the physician place can be illustrated on the video terminal of the at least one patient place.
8. The dialysis system according to claim 1, wherein a patient data file stored in the server includes indications on the dialyzer determined for a patient as well as on the settings and operational parameters thereof, and the video terminal of the at least one patient place receives the settings and operational parameters from the server and sets them at the dialyzer.
9. The dialysis system according to claim 1, wherein the input device consists of a data reader reading information on the patient, the operator, or both from a data carrier.
10. The dialysis system according to claim 1, wherein each video terminal comprises a screen with a keyboard and a computer connected with a control portion of the dialyzer.
11. A dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person, the dialysis system comprising:
 - at least one patient place having a dialyzer, a video terminal, and an ID input device for inputting an identification;
 - a central server including a data base; and
 - at least one physician place equipped with a video terminal,the video terminals and the server being interlinked with each other and configured such that information on the course of the treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input, wherein the system is configured such that information on the execution of an instruction can be input at the patient place and the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device, and wherein a patient code can be input which allocates the at least

one patient place to a patient, the video terminal of the at least one patient place is configured as a user interface for setting and changing parameters of the dialyzer, and the setting and change are stored along with the identity of the executing person.

12. The dialysis system according to claim 11, wherein the video terminals of the at least one patient place and the physician place are connected in an internal communication network, the internal communication network connected with an external communication network to which a video terminal of an external physician place is connected.

13. The dialysis system according to claim 11, wherein a symbol for calling an instruction input at the physician place can be illustrated on the video terminal of the at least one patient place.

14. The dialysis system according to claim 11, wherein a patient data file stored in the server includes indications on the dialyzer determined for a patient as well as on the settings and operational parameters thereof, and the video terminal of the at least one patient place receives the settings and operational parameters from the server and sets them at the dialyzer.

15. The dialysis system according to claim 11, wherein the input device consists of a data reader reading information on the patient, the operator, or both from a data carrier.

16. The dialysis system according to claim 11, wherein each video terminal comprises a screen with a keyboard and a computer connected with a control portion of the dialyzer.

17. A dialysis system for implementing a course of treatment for a patient as instructed by a medical personnel and executed by a person, the dialysis system comprising:

- at least one patient place having a dialyzer, a video terminal, and an ID input device for acknowledging an identification;

- a central server having a data base and a patient data file stored in the server, the patient data file including indications on the dialyzer determined for a

patient as well as on the settings and operational parameters thereof, and the video terminal of the at least one patient place receives the settings and operational parameters from the server and sets them at the dialyzer; and

at least one physician place equipped with a video terminal, wherein the video terminals of the at least one patient place and the physician place are connected in an internal communication network, the internal communication network connected with an external communication network to which a video terminal of an external physician place is connected,

the video terminals and the server being interlinked with each other and configured such that information on the course of the treatment at a selected patient place is callable and instructions for a selected patient place are adapted to be input,

wherein the system is configured such that: information on the execution of an instruction can be input at the patient place and the execution of an instruction is acknowledged by the executing person acknowledging his or her identity at the ID input device; information on occurrences may be input at the patient place and such input is effected in that the executing person acknowledges his or her identity in the ID input device; and a patient code can be input which allocates the at least one patient place to a patient, the video terminal of the at least one patient place is configured as a user interface for setting and changing parameters of the dialyzer, and the setting and change are stored along with the identity of the executing person.

18. The dialysis system according to claim 17, wherein a symbol for calling an instruction input at the physician place can be illustrated on the video terminal of the at least one patient place.

19. The dialysis system according to claim 17, wherein the input device consists of a data reader reading information on the patient, the operator, or both from a data carrier.

20. The dialysis system according to claim 17, wherein each video terminal comprises a screen with a keyboard and a computer connected with a control portion of the dialyzer.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None